



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

[Handwritten mark]

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/402,680 | 01/10/00 | SCHWARZ | BHV-313.01 |

FOLEY HOAG & ELIOT
ONE POST OFFICE SQUARE
BOSTON MA 02109-2170

HM12/0524

EXAMINER

FLOOD, M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/402,680

Applicant(s)

Schwarz et al.

Examiner

Michele Flood

Group Art Unit

1651

☒ Responsive to communication(s) filed on Jan 10, 2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 9-42 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 9-42 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1651

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 26-29 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 9 are made unclear by “biological material” and “chemical agent” because it is uncertain as to what type of biological material or what type of chemical agent Applicant intends to direct the invention. The lack of clarity makes the claim indefinite.

Claim 26 recites the limitation "an additional step for purifying said biological material" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "wherein said additional step for purifying comprises a chromatographic purification" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "further comprising an additional step of inactivating and/or depleting pathogens" in lines 1 and 2. There is insufficient antecedent basis for the limitation “depleting” in the claim.

Art Unit: 1651

Claim 29 recites the limitation "wherein said additional step is selected from the group consisting of a filtration and a heat treatment" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

The use of the trademark TWEEN® and TRITON® been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

The term "autodynamically activatable blood factor" in Claims 31-36 make the claims vague and indefinite because the term is not art-recognized. The meaning of the term is unclear and confusing, even in view of the definition, as presented on page 13, lines 15-21 of the specification. The lack of clarity makes the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Isaksson et al. (A or N).

Applicant claims a method for inactivating pathogens in a biological material by incubating the biological material with a chemical agent in the presence of an eluotropic salt corresponding to a NaCl concentration of at least 200 mM, incubation thereby being effected simultaneously with

Art Unit: 1651

or immediately after elution of the biological material. Applicant further claims a chromatographically purified preparation of a biological material.

Isaksson teaches a process for the inactivation of virus in blood products, such as a plasma protein, in a one step process using a suitable combination of temperature and a concentration of salt of at least 0.5M with a salting out effect according to the Hofmeister series. See Column 3, lines 7-25, especially lines 20-25, wherein Isaksson teaches a salt concentration of 2.0M-2.5M. The virus inactivation step includes the addition of the detergents, TWEEN® and/or TRITON® and an inactivating chemical to the protein solution, and the protein is isolated from the aqueous phase by diafiltration, desalting, chromatography, or precipitation. The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michalski et al. (B).

Applicant claims a method for inactivating pathogens in a biological material by incubating the biological material with a chemical agent in the presence of an elutropic salt corresponding to

Art Unit: 1651

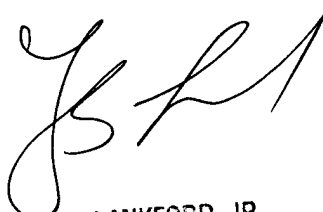
a NaCl concentration of at least 200 mM, incubation thereby being effected simultaneously with or immediately after elution of the biological material.

Michalski teaches a process for the viral inactivation and purification of the PPSB fraction of human plasma in the preparation of a human thrombin concentrate. The method taught by Michalski includes the following steps (1) adsorption of the plasma on a carrier which is prewashed in a citrate buffer containing 0.2M to 0.23M sodium chloride and a step of elution up to 0.5M sodium chloride; (2) activation of the thrombin by incubation with calcium chloride, followed by; (3) solvent/detergent viral inactivation in 1%TWEEN®; (4) purification of the thrombin by means of ion exchange chromatography; and, thrombin preparation by ultrafiltration. See Column 2, lines 45-68 and Column 3, lines 1-56. Michalski does not teach a processes for the viral inactivation and purification of a biological material, wherein the incubation of the eluted fraction is effected immediately after elution of the biological material. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the referenced teaching by reversing the order of step 1 and step 2 of the process as taught by Michalski because the order in which the process steps take place is not a critical feature of the process and will not effect the result product. Thus, the claimed invention is nothing more than the reversed steps. One of ordinary skill in the art at the time the invention was made would have been motivated to modify the Michalski method because it would have been prima facie obvious to reverse the steps as the claimed invention is nothing more than an arbitrary matter of experimental design choice.

Art Unit: 1651

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-4932. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER

mcf

May 12, 2000